REMARKS

With entry of this amendment, the claims pending in this case are claims 1-33. Claims 10, 21 and 24 are amended to delete references to figures and refer instead to sequence identifiers. Claims 26-30 are added to claim specifically the conditions of Example 3. Support for these added claims is found at paragraphs [0109] through [0112]. Claims 31-33 are restatements of claims 4, 5, 7 without use of the qualifier "about." All of the foregoing amendments are fully supported by the specification and are not believed to introduce any new subject matter.

The status of the originally presented claims is as follows: claims 1-17 are rejected; claims 21, 24 and 25 are objected to; claims 18-20 and 22-23 are noted to be in condition for allowance; claims 18-25 are noted to be free of prior art.

Entry of this amendment and reconsideration of the instant application, as amended, is respectfully requested.

Objections to the Specification

The specification is objected to for failing to comply with the sequence rules. Specifically, the drawings are objected to as containing sequences without sequence identifiers and the text of the specification is objected to for discussing sequences of 4 or more amino acids also without including a sequence identifier. Applicants have amended the drawings and the specification to include sequence identifiers SEQ ID NO: 1 to SEQ ID NO: 17. This objection is thus overcome.

Objections to the Claims

Claims 10, 21, 24 and 25 are objected to for referring to sequences by citing to a figure instead of a sequence identifier. Claims 10, 21 and 24 have been amended to refer to appropriate

sequence identifiers ("SEQ ID NO:"). Claim 25 depends from claim 24 and is thus also corrected. This objection is believed to be overcome.

The Section 112 Rejection

Claims 4, 5 and 7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the Office alleges applicants' use of "about" in connection with claim variable "m" is indefinite as it is unclear how many times the polymer unit "-(OCH_2CH_2)m-" repeats. This rejection is traversed.

The use of "about" in claims to permit "some tolerance" is a well established, acceptable practice in the Patent Office. *Ex parte King*, 82 USPQ 450, 451 (PTO Bd. App. 1948) (copy enclosed). *See* also *Merck v. Teva*, Slip. Op. 04-1005 at p. 9 (Fed. Cir. January 28, 2005) ("about" has its normal dictionary meaning of "approximately") (copy enclosed). There are a myriad of issued patents whose claims include the term "about" to qualify particular parameters. As in these issued patents, in the instant application the absolute number of repeat polymer units in applicants' formula I or the formula in claim 1 is not critical. As such, consistent with patent practice and case law, applicants' are entitled to a degree of tolerance in the meaning of "m".

Ex parte King, supra, presented an analogous fact pattern. At issue was the propriety of use of "about" to qualify the molecular weight of a binder in a sealer composition. The Examiner had rejected all claims as being indefinite stating "it is not clear what degree of tolerance should be read into the limitation 'about' in the present case." In reversing the rejection, the Board noted

> The propriety of the use of the expression "about" in claims to permit "of some tolerance" [sic]is established by long practice in the Patent Office, as shown by the numerous patents cited by the appellant wherein this expression is used in the

> claims and by hundreds of other patents of which we take judicial notice, **and it appears to us that with a range as broad as that involved in the present case the criticality of the limits can hardly be so exact as to preclude the tolerance that is afforded by this expression, especially when it was used in the original specification**. (*Citations omitted, emphasis added*).

Thus, consistent with current case law, the number of repeat units of the polymer, that is the value of "m," is not so critical in the context of the current invention, a glycoprotein conjugate, as to eliminate any degree of tolerance. Hence, the use of "about" to qualify the value of "m" in applicants' claims 4, 5, and 7 is legally and factually proper.

For the foregoing reasons, withdrawal of the Section 112 rejection of claims 4, 5 and 7 is respectfully requested.

The Section 102(e) Rejection

Claims 1-17 are rejected under 35 U.S.C. § 102(e) as being unpatentable over US Pat. No. 6,583,272 (Bailon). This rejection is traversed.

The current invention is directed to a conjugate comprising an erythropoietin glycoprotein and one poly(ethyleneglycol), such that the poly(ethyleneglycol) forms an amide bond with the N-terminal α-amino group of the erythropoietin glycoprotein. In summary, the current invention is mono-pegylated at one specific site, the α-amino group. It is a homogenus product. In contrast, Bailon permits pegylation at several sites and not only at the α-amino group. It also permits multiple pegylation, though "primarily mono-pegylated species" are preferred. *See* Bailon column 7, line 17.

That Bailon permits multiple pegylation units at multiple sites is evident from the processes described in Bailon and the species thus obtained as exemplified in the Figures. Moreover, Bailon specifically says this. At column 7, lines 8-23, Bailon notes that unmodified erythropoietin contains nine free amino groups: the amino terminal group (α-amino group) plus the ε-amino groups of the 8 lysine residues. Thus, depending on the conditions used, the erythropoietin glycoprotein can be multiple-pegylated and at any of 9 different sites. In contrast to the instant invention, Bailon does not teach protecting the ε-amino groups of the 8 lysine residues so as to ensure one pegylation unit at one specific site.

Thus, Bailon's process does not yield applicants' claimed homogenus erythropoietin species that is mono-pegylated at only the α-amino group. Consequently, Bailon is not a 102 reference. Moreover, for the foregoing reasons, if Bailon were to be asserted as a 103 reference, this rejection would also be overcome. The current invention is directed to certain species within the broader genus of Bailon. The law is well settled that species are patentable over a broader genus. *In re Baird*, 29 USPQ 2d, 1550, 1552 (CAFC 1994).

For the foregoing reasons the Section 102 rejection is improper and should be withdrawn.

The Double Patenting Rejection

Claims 1-15 are rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 10-14 of Bailon. This rejection is traversed.

As discussed above in the discussion of the Section 102 rejection, the instantly claimed invention is a selection invention over Bailon. Bailon encompasses an erythropoietin glycoprotein product genus that includes multiple pegylation (including, but not limited to, mono pegylation) at

any one or more of 9 sites (including, but not limited, to the α-amino group). In contrast, the current invention is directed to an erythropoietin glycoprotein species that is mono-pegylated at only the α-amino group. The pending claims in the current application are thus not obvious over those of Bailon. Moreover, infringement of the issued Bailon claims would not necessarily mean that there would be infringement of the current claims. For all of these reasons, the double patenting rejection of currently pending claims 1-15 over Bailon is improper and should be withdrawn.

Similarly, claim 16 of the instant application, which is directed to a pharmaceutical composition comprising a conjugate of claim 1 is rejected under the doctrine of obviousness-type double patenting as being unpatentable over claim 1 of Bailon (6,583,272). This rejection is also traversed.

The basis for the Section 102 rejection and the double patenting rejections is asserted to be that the species of the current invention is/are "encompassed" by the genus of Bailon. However, as already mentioned above, the fact that a later species is within an earlier claimed broader genus is not in of itself a proper basis for a double patenting rejection. The current record is devoid of any case or regulation that would support this rejection.

For the reasons stated above with respect to claims 1-15 of the instant application, the instantly claimed conjugates are mono-pegylated at the α-amino group. This is a patentable feature over the genus of Bailon, both the specification and claims. Moreover, claim 1 of Bailon is not directed to a pharmaceutical composition. This rejection is improper and should be withdrawn.

Miscellaneous

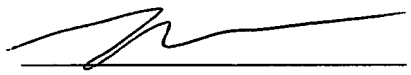
For completion, the Examiner's attention is directed to co-pending, co-owed USSN 09/853,731(CD 20619 US) and 10/780,297 (CD 20619 US1).

Conclusion

In view of the above amendments and the foregoing remarks, it is respectfully submitted that the instant application is in condition for allowance and prompt allowance of the application is solicited.

Applicants believe that no fee is due with this communication. However, should the Patent Office determine that a fee is owed, or a credit is due to applicant, the Patent Office is hereby authorized to charge any required fees, including any extension of time and/or excess claim fees, or credit any overpayment, to applicant's Deposit Account 08-2525 as appropriate.

Respectfully submitted,



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Attachments

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